



MolMed successfully completes a Phase I/II clinical trial of TK therapy in bone marrow stem cell transplantation for high risk acute leukemia

Milan, Italy – December 13, 2005 – MolMed S.p.A., a biotech company focused on novel anticancer therapies, announced today unprecedented improvement in survival of patients receiving bone marrow transplantation from a partially incompatible family donor for high risk acute leukaemias. In this context, the introduction of MolMed TK therapy promotes rapid and sustained immune reconstitution, thus abating transplant related mortality.

These impressive results, presented at the 47th Annual Meeting of the American Society of Hematology (ASH) in Atlanta (USA), are the outcome of a European multicentric Phase I/II study (MM TK007), conducted in Italy, UK and Israel and involving a total of 30 patients affected by acute leukemia and receiving hematopoietic stem cell transplantation (HSCT) from a haplo-identical family donor. Standard haplo-HSCT is limited by delayed immune reconstitution, resulting in a high rate of late mortality and disease relapse. The adjunctive treatment with TK proved to be an effective tool for promoting immune reconstitution and improves safety and efficacy of haplo-HSCT, thus increasing feasibility of transplantation from partially incompatible family donors. MolMed plans to conduct a similar trial at the MD Anderson Cancer Center in Houston (USA), and to start a Phase III randomised multicentric study in 2006.

About acute leukemia

High risk acute myeloid leukemia is a hematological malignancy for which the best chance of cure is transplantation of hematopoietic stem cells from a healthy family donor. However, feasibility and effectiveness of HSCT are heavily limited by the shortage of family fully compatible donors, which are available only for 1/3 of the patient population. Partially compatible (haplo) donors are available for nearly all patients. However, safety and efficacy of this type of transplant is limited by a high rate of transplant related mortality associated with delayed immune reconstitution.

About TK therapy

Tk therapy is based on the use of genetically engineered lymphocytes from the haplo-identical donor utilized in association with the HSC transplant. TK donor lymphocytes allow to control the main complications associated with haplo-HSCT, thereby increasing both patients' survival and the number of available bone marrow donors.

Orphan drug designation for TK has been granted in the European Union in 2003 and in the U.S. in 2005. MolMed's strategic partner *Takara Bio Inc.* (Japan) is developing TK for the Asian markets.

About MolMed

MolMed S.p.A is a biotechnology company focused on R&D and production of novel anticancer therapies. MolMed has additional new anticancer agents undergoing clinical validation, for solid tumours. ARENEGYR, the first of a new class of vascular targeting compounds, addressed to destroy the tumor vasculature; and M3TK, a therapeutic vaccine based on efficient dendritic cell in vivo loading of tumor associated antigens. MolMed's clinical pipeline is supported by a broad portfolio of therapeutic candidates. MolMed is headquartered at the San Raffaele Biomedical Science Park in Milan, Italy.

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